

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

11/25/02 P 3:03

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

THIS DOCUMENT RELATES TO
ALL ACTIONS

MDL NO. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

CONSOLIDATED MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS
THE MASTER CONSOLIDATED CLASS ACTION COMPLAINT

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Plaintiffs here – a handful of individuals, union benefit plans, and associations – seek to use this case to override years of federal policy-making and to trump the current, ongoing political debate between the Executive Branch and Congress on Medicare drug pricing. Purporting to represent more than 200 million Americans and untold thousands of American businesses who pay for prescription drugs, plaintiffs allege that Medicare and private health plans have been systematically “manipulated” by the nation’s prescription drug manufacturers. The vehicle for this alleged fraud, according to plaintiffs, is an undefined term called “average wholesale price” (“AWP”).

AWPs for prescription drugs are reported by independent publishing companies. Under the Medicare program, these published AWP’s are used to calculate the amount doctors and other healthcare providers are reimbursed for drugs they administer. The providers’ actual acquisition costs are often substantially lower than AWP, and the providers keep the “spread.” Many government reports, which the Court may consider in this motion, conclusively demonstrate that Congress and the Executive Branch have been well aware for decades that published AWP’s are often substantially higher than the actual acquisition costs of drugs. Yet the government knowingly and intentionally established this system and has left it in place because of a policy judgment that providers should receive a premium on drug reimbursement to compensate for Medicare’s underpayment for the providers’ professional services. Thus, plaintiffs are challenging not fraud, but long-standing government policy set by the political branches of government.

Plaintiffs contend that by not reporting AWP’s at the level of providers’ actual acquisition costs (or something close to that), the defendant manufacturers violated the federal racketeering statute and the consumer fraud statutes of eleven states. Their claims fail on several fronts.

First, there can be no fraud where the government established and has maintained AWP-based reimbursement with full knowledge that published AWPs often bear no relationship to actual acquisition costs. Indeed, the relief plaintiffs seek would require this Court to exceed the bounds of its jurisdiction and invade the province of the elected branches, because in order for plaintiffs to prevail, the Court must rule that AWP is something other than what Congress and the Executive Branch have decided it should be. Such an action would be particularly inappropriate because Congress and the Executive Branch are currently considering changing Medicare's AWP-based system of reimbursement.

Second, even if the Court could wade into this policy thicket, there is no RICO claim. In addition to the absence of any fraud, plaintiffs are indirect purchasers whose alleged injuries (high payments for drugs) were not caused directly by defendants. Instead, the intervening actions of the physicians who decided how much to charge for drugs and of the government (or private health plans) that established the reimbursement rates break any causal connection between defendants' alleged actions and plaintiffs' alleged injuries. In addition, plaintiffs' dizzying array of putative RICO enterprises fails as a matter of law. Finally, the RICO claims are deficient because many of the key fraud allegations fail to satisfy Rule 9(b), especially the few allegations about marketing the spread of drugs outside of Medicare. The original AWP cases that were transferred to this Court by and large were restricted to a few drugs under Medicare. Plaintiffs now allege, with absolutely no specifics, that thousands of non-Medicare "brand name" drugs, sold through unidentified pharmacy benefit managers, are also at issue. Before plaintiffs can be allowed to commence such enormous litigation, Rule 9(b) requires far greater specificity as to the allegedly fraudulent conduct of each defendant.

Third, the Medicare statute and regulations preempt the state law claims related to that program, and ERISA preempts the state law claims of certain plaintiffs. Like the RICO claims, the state law claims also fail for lack of fraud and direct causation.

STATEMENT OF THE CASE

The legislative and regulatory history of Medicare reimbursement for prescription drugs reveals two indisputable conclusions that are fatal to plaintiffs' claims: (1) Congress and the Executive Branch have known for many years that the published AWP's frequently are higher than the prices at which providers actually purchase drugs; and (2) with this knowledge, Congress has made repeated policy decisions to retain AWP as the reimbursement benchmark because it wanted to ensure adequate overall reimbursement for providers.¹

A. Medicare Part B Coverage For Drugs

The Medicare program provides basic and supplementary health insurance to individuals age 65 and older and to other qualifying individuals. *See* Master Consolidated Class Action Complaint ("Master Complaint" or "Cplt.") ¶ 141; *see also* 42 U.S.C. §§ 1395-1395pp (2000). The Medicare program is administered by the Center for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), a branch of the Department of Health and Human Services ("HHS"). Cplt. ¶ 142. Congress has authorized

¹ For the Court's convenience, defendants have submitted a Revised Appendix of Exhibits containing many of the public record documents cited herein. The Court may rely on such documents without transforming this motion into one under Rule 56. Under Rule 12(b)(6), the Court may consider "matters of public record," such as "letter decisions of government agencies" and "published reports of administrative bodies." *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993), *aff'd* 215 F.3d 407 (3d Cir. 2000). Further, to the extent defendants' motion relies on Rule 12(b)(1), the Court is also free to consider these public materials without converting the motion into one for summary judgment. *See Dynamic Image Techs., Inc. v. United States*, 221 F.3d 34, 38 (1st Cir. 2000).

the Secretary of HHS (the “Secretary”) to promulgate regulations setting limits on the levels of costs that Medicare will reimburse. *Id.*

Part B of Medicare establishes a voluntary, federally subsidized program of supplemental medical insurance that covers, *inter alia*, certain limited categories of outpatient drugs, including physician-administered drugs (“Covered Drugs”). Cplt. ¶ 143; *see* 42 U.S.C. § 1395k(a)(1).

Part B generally provides beneficiaries coverage for 80 percent of the allowable amount for a particular medical service or pharmaceutical. Cplt. ¶ 149; 42 U.S.C. § 1395l(o). The beneficiary is responsible for the remaining 20 percent as a co-payment. *Id.*

The Secretary contracts with private insurance carriers to administer and process Part B claims. 42 U.S.C. § 1395u. Since 1992, these carriers have reimbursed many healthcare providers for Covered Drugs using a formula set forth in federal regulations that is based on AWP. Cplt. ¶ 133; 42 C.F.R. § 405.517 (1992) (now superceded).² In 1997, Congress codified the current AWP reimbursement standard and mandated that payment for Covered Drugs be “based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.” 42 U.S.C. § 1395u(o); *see* 42 C.F.R. § 405.517 (1998) (Ex. 30).³ AWP’s are published by several industry compendia. Cplt. ¶ 134.⁴ The term “average wholesale price” is not defined either in the Medicare Part B statute or the accompanying regulations. Likewise, there are no regulations directing pharmaceutical

² In some instances, most notably in the hospital outpatient setting, Covered Drugs are not reimbursed at rates tied to AWP. For purposes of the present motion, however, we assume the correctness of the oversimplified allegations in the Master Complaint.

³ For multi-source drugs, including generics, the average wholesale price is the median of the published AWP’s for all generic forms of the drug or the lowest published AWP of the brand name forms, whichever is lower. *See* 42 C.F.R. § 405.517(c) (Ex. 30).

⁴ For purposes of this motion, defendants accept, as they must, the allegations that defendants “reported” AWP’s to the publishing companies.

manufacturers to report AWP to the services that publish them, let alone describing how AWP are to be calculated.

Manufacturers do not sell their drugs to Medicare, and the Medicare program does not pay the manufacturers. Rather, defendants sell their drugs to wholesalers, HMOs, physicians, pharmacies, and other providers; the providers administer the drugs and file claims for reimbursement with the carriers; and the carriers pay the providers. Similarly, Medicare beneficiaries do not pay their 20% co-payments to the defendants, but to the health care providers who bill them.

B. Prior To Medicare's Use Of AWP In The Early 1990s, The Government Had Been Aware For Years That The Published AWP Often Exceeded The Prices Paid By Providers For Drugs.

Stripped of its inflammatory adjectives and conclusory assertions, the Master Complaint alleges that reported AWP exceeded the actual cost to providers for drugs. But long before Medicare adopted AWP as the benchmark for Part B drug reimbursement in 1992, both Congress and HHS knew that AWP often substantially exceeded provider acquisition costs. Prior to 1992, HHS had considerable experience with AWP through the Medicaid program, the health benefits program for the poor that is jointly funded by the States and the Federal government. *See* 42 U.S.C. § 1396 *et seq.* Under Medicaid, federal regulations for years have required reimbursement levels for certain prescription drugs to be the lesser of the provider's "usual and customary charges," or "estimated acquisition costs plus reasonable dispensing fees established by the [state Medicaid] agency." 42 C.F.R. § 447.331(b)(1), (2) (2002). The regulations give

state Medicaid programs latitude in devising a methodology to determine “estimated acquisition costs,” and many states used AWP as a proxy for estimated acquisition costs.⁵

From 1984 to 1990, HHS repeatedly criticized state Medicaid agencies that based prescription drug reimbursement on AWP on the ground that AWP did not reflect actual acquisition costs. In 1984, HHS’s Office of Inspector General (“HHS IG”) issued a report urging Medicaid officials “to stop the present widespread use of average wholesale prices (AWP) in determining program reimbursement for prescription drugs.” Ex. 31 at 10,192. The HHS IG explicitly recognized that “[w]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price.” *Id.* at 10,193 (emphasis added). The HHS IG further explained that the AWP “list price” “does not reflect several types of discounts . . . rebates, or free goods that do not appear on the pharmacists’ invoices.” *Id.* at 10,206. Because “pharmacies do not purchase drugs at the AWP published” in industry compendia, “AWP cannot be the best – or even an adequate – estimate of the prices providers generally are paying for drugs.” *Id.* Accordingly, the HHS IG recommended that HHS revise its regulations to “eliminate the use of AWP” and require state Medicaid programs to use alternative methods to calculate estimated acquisition costs. *Id.* A 1989 HHS IG report repeated the findings of the 1984 report.⁶

⁵ See HHS IG, *Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs*, Medicaid Action Transmittal, No. 84-12, 1984-2 Medicare & Medicaid Guide (CCH) ¶ 34,157, at 10,191 (Sept. 1984) (Ex. 31).

⁶ See HHS IG, *Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program* [1989-1990 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 38,215 (Oct. 1989) (Ex. 41). Also in 1989, the Senate Special Committee on Aging issued a report recognizing that AWP exceeds actual drug prices. The Committee reported that the Department of Veterans’ Affairs “achieves an average discount of 41% off . . . AWP . . . for single source drugs . . . and an average of 67% off the published AWP for multiple source drugs.” Staff of Senate Special Comm. on Aging, 101st (continued...)

Consistent with these reports, HCFA disapproved the Medicaid plans of at least three states that proposed to use undiscounted AWP's to set drug reimbursement rates on the ground that AWP exceeded acquisition cost.⁷ In one of these cases, the government filed a brief quoting a HCFA official who stated that "AWP has become like the 'sticker price on an automobile. It is the very highest price that anyone would be expected to pay for a drug product.'" Brief For Respondent, *Louisiana v. United States Dep't of Health & Human Servs.*, No. 89-4566, at 23 n.9 (5th Cir. Jan. 12, 1990) (Ex. 53).

In 1990, Congress enacted legislation that required manufacturers participating in the Medicaid program to report to HCFA the "average manufacturer's price" for each drug and the "best price" at which certain drugs are sold. 42 U.S.C. § 1396r-8(b)(3)(A)(i). These terms, unlike AWP, are explicitly defined by statute. 42 U.S.C. § 1396r-8(k)(1) & § 1396r-8(c)(2)(C). Thus, for more than a decade, HCFA has had detailed pricing data from many drug companies.

C. Congress And HHS Decided To Use AWP For Medicare Reimbursement Knowing That Published AWP's Often Exceeded Provider Acquisition Cost.

1. HHS' Adoption And Continued Use Of AWP From 1991-1996.

In 1989, Congress amended the Medicare Act to provide (effective in 1991) reimbursement for certain additional medical services. The amendment provided that Medicare would reimburse for those services based on the physicians' "actual charge" (*i.e.*, whatever physicians actually charged) or pursuant to a fee schedule to be developed by HCFA. *See*

Cong., *Prescription Drug Prices: Are We Getting Our Money's Worth?* 11 (Comm. Print 1989) (emphasis added) (Ex. 1). In addition, "hospitals, Health Maintenance Organizations, and nursing homes that contract with wholesalers . . . achieve discounts up to 99% off . . . AWP." *Id.*

⁷ *See Louisiana v. Dep't of Health & Human Servs.*, 905 F.2d 877, 879-80 (5th Cir. 1990) (discussing how AWP exceeds acquisition cost); *In re Arkansas Dep't of Human Servs.*, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991); *In re Oklahoma Dep't of Human Servs.*, 1991 WL 634860 (HHS Dept. App. Bd. Aug. 13, 1991).

Pub. L. No. 101-239 § 6102(a) (1989) (codified in part at 42 U.S.C. § 1395w-4(a) & (j)(3)).

HCFA did not, however, establish a specific fee schedule for Covered Drugs administered incident to physician services. Instead, notwithstanding its experience with AWP-based reimbursement in the Medicaid program, HCFA in 1991 proposed a rule instructing carriers “to base payment for drugs at 85% of the national [AWP] of the drug (as published in the Red Book and similar price listings).” *See* 56 Fed. Reg. 25,800 (June 5, 1991).

In response to this proposed regulation, HCFA “received a great many comments . . . primarily from oncologists indicating that our 85 percent standard was inappropriate.” 56 Fed. Reg. 59,524 (Nov. 25, 1991). These doctors argued that Medicare should pay them more than the price they paid to purchase drugs in order to make up for the fact that Medicare underpays them for their professional services and to cover overhead costs, such as inventory, waste, and spoilage associated with chemotherapy drugs. *Id.* Commenters advised that unless Medicare paid oncologists a higher amount, some oncologists would stop administering chemotherapy in their own offices and would instead do so only in hospital settings, leading to higher overall costs to Medicare. *See id.*

In response to these comments, HCFA rejected its proposed 85% of AWP rule in favor of a final regulation that set the allowable Medicare reimbursement amount as the lesser of (1) 100% of AWP, or (2) estimated acquisition cost (“EAC”), as determined by Medicare carriers’ surveys of the prices paid for the drug, taking into account additional cost factors such as inventory, waste, and spoilage. *See id.* at 59,621, *codified at* 42 C.F.R. § 405.517 (1992) (now superseded); Cplt. at ¶ 144. However, Medicare carriers were unable to compile accurate EAC

data.⁸ As a result, reimbursement at 100% of AWP continued from 1991 through 1997 despite at least fourteen studies by HHS showing that AWP often far exceeded the providers' acquisition costs. *See* Exs. 29, 39-40, 42-52. One of these studies, for example, concluded that "AWP is not designed to reflect physicians' costs," which for some drugs were found to be as much as 83% lower than the published AWP. HHS IG, *Physicians' Costs for Chemotherapy Drugs* at 5 and App. II & III (Nov. 1992) (Ex. 29).⁹

2. In 1997, Congress Rejected the Administration's Proposal To Abandon AWP And Set Reimbursement At 95% Of AWP.

In enacting the Balanced Budget Act of 1997 (the "BBA"), Congress rejected the Administration's proposal to set reimbursement for Covered Drugs at the provider's actual cost and instead reset the Medicare reimbursement rate for covered drugs at 95% of AWP. The legislative and regulatory history generated during this period leaves no doubt that Congress and the Administration fully understood that published AWP exceeded -- often substantially -- providers' actual acquisition costs.

The Administration initially proposed reducing Medicare drug reimbursement to the amount the provider actually paid for the drug.¹⁰ In support of this proposal, Secretary of HHS

⁸ *See Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers: Joint Hearing Before the Subcomm. on Health and the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 107th Cong. 88 (Sept. 21, 2001) (Ex. 26); Letter from Donna Shalala, Secretary, HHS, to Hon. Thomas Bliley, Chairman, House Comm. on Energy and Commerce (May 31, 2000) (Ex. 24).

⁹ The difference, or "spread," between AWP and provider acquisition costs was well publicized in the press as well. In June 1996, for example, an article appeared in *Barron's* that described AWP as "Ain't What's Paid." Bill Alpert, *Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals?*, *Barron's*, June 10, 1996, at 3 (Ex. 37). *See* Exs. 22, 34, 38, 54 (additional press reports).

¹⁰ *See President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid and Welfare: Hearings Before the Senate Comm. on Finance*, 105th Cong. 265 (1997) (written submission of Donna Shalala, Secretary, HHS) (Ex. 21).

Donna Shalala explained to Congress that “AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a ‘sticker’ price set by drug manufacturers and published in several commercial catalogs.” Ex. 21 at 265. Secretary Shalala asserted that “physicians should be paid for their professional services and not derive a profit from drugs furnished incident to their professional services.” *Id.* She also pointed out that “the current payment rules for drugs allow an increase in the AWP even if the cost to the physician remains constant. This creates an incentive for physicians to furnish the most profitable drugs.” *Id.* The Administration proposed to “remove this incentive.”

Despite these explicit policy arguments, Congress rejected the Administration's proposal to peg Medicare reimbursements to actual acquisition costs. Instead, Congress amended the Medicare Act to set allowable reimbursement at 95% of AWP and to eliminate estimated acquisition cost as a criterion for payment. *See* Pub. L. No. 105-33 § 4566(a) (1997) (codified at 42 U.S.C. § 1395u(o)). Although Congress did not include a definition of AWP in the statute, the legislative history reveals that Congress recognized that reliance on AWP's caused Medicare reimbursements far in excess of acquisition costs. *See* H.R. Rep. No. 105-149, at 1354 (1997) (HHS IG “reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs.”) (Ex. 2); S. Rep. No. 105-30, at 158 (1997) (Medicare pays “substantially more than most other payers for prescription drugs.”) (Ex. 3); *see also* Exs. 39-52 (HHS IG reports). Bound by this legislation, HCFA instructed its carriers to continue to reimburse covered drugs on the basis of AWP's published in industry compendia. *See* HCFA Transmittal Nos. AB-97-25 (Jan. 1998) & AB-98-76 (Dec. 1998) (Exs. 32 & 33).

3. In 1998 And 1999, Congress Rejected Administration Proposals To Abandon AWP.

Shortly after passage of the BBA, President Clinton criticized Congress' AWP-based Medicare reimbursement policy in a radio address to the nation. But even as he characterized the statutory reimbursement system as wasteful and abusive, President Clinton also stated there was nothing illegal about it:

Sometimes the waste and abuse aren't even illegal; they're just embedded in the practices of the system. Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs – overpayments that cost taxpayers hundreds of millions of dollars Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price – the so-called sticker price – for the drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price.

White House Office of Press Secretary, Remarks by the President in Radio Address to the Nation, 1997 WL 767416, at *1-2 (Dec. 13, 1997) (emphasis added) (Ex. 23). To remedy these “overpayments,” the President announced, “I’m sending to Congress again the same legislation I sent last year – legislation that will ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients.” *Id.* at *2.

Congress did not enact the legislation proposed by the President. Indeed, in the two years following enactment of the BBA, Congress refused to act on at least ten bills that were introduced in the House or Senate that proposed to reduce Medicare drug reimbursements by switching to a formula based on the provider's actual acquisition cost or by setting reimbursement at 83% of AWP. *See* Exs. 6-15.

4. **In 2000, Congress Prevented HCFA From Redefining AWP To Approximate Actual Provider Acquisition Cost.**

After legislative efforts to eliminate AWP-based reimbursement failed, HCFA tried administratively to accomplish the same objective. In May 2000, Secretary Shalala informed Congress that HCFA was preparing to instruct Medicare carriers to cease using published AWP and to use instead lower price data recently estimated through a government-sponsored pricing survey for certain drugs. *See* Letter from Donna Shalala, Secretary, HHS, to Hon. Thomas Bliley, Chairman, House Commerce Comm. (May 31, 2000) (Ex. 24).

Congress acted swiftly to stop the Administration's effort to unilaterally change the way AWP is determined and thereby change the reimbursement rates for Medicare drugs. In July 2000, 89 members of Congress wrote Secretary Shalala objecting to her plan to abandon the use of published AWP in favor of alternative prices that purportedly approximated those actually paid by physicians for drugs: "Congress in 1997 instructed the Department to base reimbursement for drugs on 95% of AWP, a term widely understood and indeed defined by Department manuals to reference amounts reflected in specified publications [T]he Department's unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate." Letter from 89 Members of Congress, to Donna Shalala, Secretary, HHS 1-2 (July 28, 2000) (Ex. 25). These 89 Members also noted that oncologists rely on Medicare paying a markup on drugs to offset the fact that Medicare underpays them for their professional services: "If reimbursement for drugs is drastically reduced, many physicians will be unable to continue providing cancer care in their offices, and patients will be deprived of a humane, convenient and cost-effective treatment option." *Id.* at 1.

In addition, then-Senator Ashcroft introduced a bill called the "Cancer Care Preservation Act" to bar HCFA from implementing "any reduction to the rates of reimbursement for

outpatient cancer therapy services under the Medicare program . . .” 146 Cong. Rec. S8023 (Sept. 5, 2000) (Ex. 4). He complained that HCFA was intending “to reduce drastically Medicare reimbursement rates for cancer drugs by unilaterally changing the definition of ‘average wholesale price,’ which is at the heart of the current reimbursement formula.” *Id.* at S8022. He argued that Medicare drug reimbursement should exceed the price paid by physicians and hospitals because “these margins . . . help cover costs for professional services, which are inadequately reimbursed . . .” *Id.* Senator Ashcroft warned that HCFA's plan to cut drug reimbursement by “changing the definition” of AWP would “force doctors to send seniors with cancer out of the community settings” and into more expensive hospital settings, which would cause overall Medicare spending to rise. *Id.* See also 146 Cong. Rec. S8093 (Sept. 6, 2000) (similar statement of Sen. Abraham) (Ex. 5).

In November 2000, the Administration bowed to Congressional pressure. HCFA suspended its instructions to carriers to use alternative pricing data and directed carriers to return to using “AWP data from your usual source.” HCFA Transmittal No. AB-00-115 (Nov. 17, 2000) (Ex. 35). Not content with HCFA's retreat, Congress enacted legislation barring the Secretary of HHS from “directly or indirectly decreas[ing] the rates of reimbursement” for drugs covered by Part B until the Comptroller General (*i.e.*, the General Accounting Office) studied the issue of Medicare drug reimbursement. Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (“BIPA”), Pub. L. No. 106-554 § 429(c), 114 Stat. 2763 (2000) (Ex. 16). BIPA also directed the GAO to comment on whether changes to Medicare payment for professional services would be warranted if the drug reimbursement methodology were changed. See *id.* at § 429(a)(3). In response to this legislation, HCFA instructed the carriers to continue to

use AWP's published in industry compendia. *See* HCFA Transmittal No. AB-01-66 (May 3, 2001) (Ex. 36).

5. Congress And HHS Are Currently Exploring How Best To Revise Medicare Drug Reimbursement.

Since BIPA, Congress and HHS have continued actively to explore ways to revise Medicare drug reimbursement. In September 2001, the GAO submitted the drug reimbursement study required by BIPA.¹¹ Since then, Congress has held three hearings specifically on the issue of revising Medicare reimbursement for drugs. At the March 14, 2002 hearing, CMS Administrator Thomas Scully testified that “[t]he current system, which results in Medicare and beneficiaries paying excessive prices for certain prescription drugs, must be fixed. At the same time, we need to be certain that Medicare pays providers appropriately for their services when they furnish drugs to beneficiaries.”¹²

There are currently several bills before Congress that would revise how Medicare reimburses for drugs. *See* Exs. 17-19. Yet, as of late 2002, Medicare remains the only public payer that does not rely on “actual transaction prices” reported by drug manufacturers. Ex. 20 at 24-25. This state of affairs has been dictated by Congress and is the result of its efforts to balance competing policy interests.

¹¹ *See* GAO, *Payments for Covered Outpatient Drugs Exceed Providers’ Cost* (Sept. 21, 2001) (Ex. 20).

¹² *See* Testimony of Thomas Scully, *Reimbursement & Access To Prescription Drugs Under Medicare Part B, Senate Finance Committee Subcommittee on Health 2* (March 14, 2002) (Ex. 27); *see also* Testimony of Thomas Scully, *Reimbursement & Access To Prescription Drugs Under Medicare Part B, House Ways and Means Committee Subcommittee on Health 1* (Oct. 3, 2002) (same) (Ex. 28).